REMARKS

Claims 1-17 are currently pending in this application. No new matter is presented.

35 U.S.C. § 102 Rejections Overcome

Claims 1-17 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 5,487,901 and 5,650,169 ("Conte"). Applicants respectfully traverse the rejection.

In order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). Specifically, the Examiner states that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient formulated for immediate release, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being *almost* completely coated with an impermeable insoluble polymeric coating (*emphasis added*). (*See*, Office Action at page 2). The Examiner asserts that the method by which the tablet of claims 1-17 is made is different from the method described in Conte but that the process by which the claimed product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of Conte. (*See*, Office Action at page 3). Applicants respectfully traverse the rejection.

Applicants submit that the process by which the therapeutic tablet system described in claims 1-17 is made imparts functional and structural limitations to the claimed product that distinguish it from the product of Conte. Applicants submit that the process of making the therapeutic tablet system of claims 1-17 causes structural differences between this system and the tablets taught in Conte giving the therapeutic tablet system of claims 1-17 greater stability and a more advantageous release profile for constant steady release of the drug. (*See* Exhibit A and B).

Applicants submit that it is the differences in the process of making the tablets of claims 1-17 that account for significant difference in the release profile found between the tablets of the claimed invention and those of Conte. The tablets in Conte, on average, release over 30-50% of the active ingredient within 15-20 minutes and after the initial release, the release profile tends to

flatten out until later when a subsequent release occurs, *i.e.*, the release of active ingredients occur in pulses. (*See*, Exhibit A, and Conte Tables 1-9). In contrast, the claimed tablet has a substantially linear drug release rate, not "in sequential pulses," where less than 10% of the drug is released in the first 15-20 minutes, and approximately 50% drug is released in 3-4 hours and the release continues for approximately 7-8 hours. (*See*, Exhibit B). This linear controlled rate is achieved due to the incision on one face of the tablet. The conclusion that the predetermined incision(s) is the critical factor in establishing the observed release profile is supported by the data that the active ingredient is released at different rates as a function of the area of the hole made in the coating. At equal compositions, from the filmed tablet with the circular hole of 7.0 mm in the coating (equal to 38.5 mm^2) the active ingredient is released at a greater rate with respect to the system with the hole of 5.0 mm (equal to 19.5 mm^2). (*See* Exhibit B). The data in support of the current invention convincingly demonstrate that, even when the excipients and active ingredients in the tablet are varied, the predetermined size of the incision determines the release profile, which remain effectively as a linear, controlled and steady rate. The release profile in the tablet of Conte also are affected by the abrasion generated on the tablet, not the excipients or active ingredients. The release profile of active ingredients in the tablets disclosed in Conte remains in "sequential pulses" irrespective of the excipients used. (*See* Exhibits A and B). Thus, one would be compelled to infer that, controlling for the excipients in the tablets of the current invention, the only difference in release rate are attributable to the size of the incisions. Applicants submit that it is the incision(s) on the claimed tablet, which comprise an impermeable coating that fully covers the active ingredients and remains intact until the moment of use so that it protects the active ingredients contained therein, which alters the release profile, with a pre-determinable and programmable release rate, which differs in its pattern from the release profiles of Conte, *i.e.* a structural and functional limitation. Applicants submit that the process of making the therapeutic tablet system of claims 1-17 gives the system a more advantageous release profile for constant steady drug release than the tablets taught in Conte.

Applicants submit that the incision(s) delimited film coating of the tablet of claims 1-17 remain intact before contact with aqueous fluids. Thus, the incisions of the therapeutic tablet system of claims increase the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration. (*See*, Specification and Declaration

under 37 C.F.R. § 1.132 of Ubaldo Conte submitted herein). Whereas the tablet in Conte does not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient exposed. (*See*, Conte at Column 6, lines 1-4). Applicants submit that the tablet of the claimed invention is different than the tablet in Conte, as Conte does not provide a method to stabilize the active ingredient exposed by the abrading process.

Applicants submit that the process for making the therapeutic tablet system described in claims 1-17 imparts functional and/or structural limitations to the product that distinguish it from the product of Conte. Thus, Conte cannot anticipate claims 1-17. Reconsideration and withdrawal is requested.

Additionally, claims 1-17 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by US 6,599,284 ("Faour"). Applicants disagree. As stated above, in order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). The Examiner indicates that Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredients, and an inner layer or core containing active ingredient, and the dosage form comprises a passageway formed by a incision, which is incised in both the top and bottom layers. (*See*, Office Action at page 5). Applicants traverse this rejection with respect to the claims as amended herein.

Specifically, Applicants submit that Faour teaches and claims that the passageway increases the release rate of the active agent during use, which is not taught in the current claims. (*See*, Faour at column 4, lines 48-50). This linear controlled rate observed in the tablet of claims 1-17 is achieved due to the incision on one face of the tablet, unlike in Faour where both the top and bottom layers are incised. Applicants submit that Faour does not teach each and every limitation of and thus cannot anticipate them. Reconsideration and withdrawal is requested.

CONCLUSION

On the basis of the foregoing amendment and remarks, Applicants respectfully submit that the pending claims are in condition for allowance and a Notice of Allowance for the pending claims is respectfully requested. If there are any questions regarding this application that can be handled in a phone conference with Applicants' Attorneys, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted, Reg. 100,558,032

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